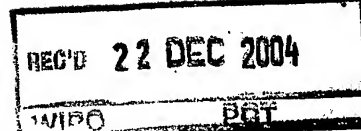


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(71) Sökande *Pronova Biocare AS, Lysaker NO*  
Applicant (s)

(21) Patentansökningsnummer *0303513-6*  
Patent application number

(86) Ingivningsdatum *2003-12-19*  
Date of filing

Stockholm, 2004-12-08

För Patent- och registreringsverket  
For the Patent- and Registration Office

*Hjördis Segerlund*

Hjördis Segerlund

Avgift  
Fee 170:-

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DOCUMENT**  
SUBMITTED OR TRANSMITTED IN  
COMPLIANCE WITH RULE 17.1(a) OR (b)

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**Huvudfaxen Kåssan**

## Technical field of the invention

The present invention comprises a number of aspects. According to the first aspect of the present invention, a use of a new medical product for controlling body weight reduction, for treatment of obesity or an overweight condition is disclosed. According to a second aspect of the present invention, a method for treatment of obesity, an overweight condition or for controlling body weight reduction, is disclosed. According to a third aspect of the invention, a use of a food stuff or food supplement for controlling and supporting body weight reduction in a human or an animal, is disclosed. Moreover, according to a fourth aspect of the present invention, a dietary product for non-medical treatment of obesity, an overweight condition and/or for supporting and controlling weight reduction, is disclosed. Additionally, according to a fifth aspect of the present invention, a use of a dietary food stuff or food supplement for controlling and supporting weight reduction, is disclosed. Finally, according to the sixth aspect of the present invention, a method for supplementing a dietary food stuff, is disclosed. The aspects above are based on at least one of the following features: a fatty acid composition comprising at least one of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or any combinations thereof, or a step of adding a fatty

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acid composition comprising at least one of EPA and DHA  
or any combinations thereof, to a supplement product.

### Background art

5 More individuals are becoming overweight and obese, a  
condition now considered to be the most common  
nutritional disorder in the industrialised world today.  
Overweight and obesity can be defined by a body-mass  
index exceeding 25 or 30. Normal values range from 18 to  
10 25. In the US 34% of the population is overweight and  
another 27% is obese. This means that more than 60% of  
the entire population in the US has what can be defined  
as having a weight problem, which is likely to cause  
severe health problems, such as hypertension and elevated  
15 blood lipids, all risk factors for cardiovascular  
disease.

Overweight and obesity are caused by an imbalance  
between energy intake and energy use. In the  
industrialised world we tend to eat too much and engage  
20 in physical activities too little. However, the  
likelihood of becoming fat under these conditions is not  
the same for everyone, as witnessed by the fact that slim  
individuals exist under the same conditions as those who  
are overweight. Furthermore, the revelation that  
25 nutritional factors may control gene expression has  
opened up the possibility of developing novel therapeutic  
alternatives to treat obesity. The major problem in  
therapeutic strategies aimed to treat obesity and  
decrease body fat deposit is that such strategies act  
30 against potent and multiple mechanisms evolved in order  
to store metabolic energy and support survival under the  
periods when nutrition is scarce.

## Huyudfoxen Kaseen

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saturated fatty acids. The differences in three dimensional structure between fatty acids means that while the PUFA's can act as signalling agents to the cell, switching gene transcription off or on, the

5 saturated fatty acids are not recognised and have no effect. In the laboratory calorimeter all fats irrespective of their saturated or unsaturated nature generate 9 kcal of energy per gram, but when part of the diet, PUFA's give completely different net effects on

10 metabolic energy production and weight gain compared to the saturated fatty acids. Thus, saturated fatty acids are the main source of energy in the human body, while PUFAs fulfil a different function. PUFA's are derived mainly from seeds, nuts or fish oil. They may have their

15 first double bond located either three, six or nine carbon atoms away from the chain end. Thus, they are known either as omega-3, omega-6 and omega-9 fatty acids, or n-3, n-6 and n-9 fatty acids. Humans can not synthesise fatty acids with double bonds at the 3 or 6

20 location making these fatty acids essential dietary components. In certain cases both types of PUFA's may have the same action. One example is the effects of PUFA's on suppressing lipid synthesis in the liver while at the same time up-regulating fatty acid oxidation in

25 the liver and skeletal muscle. It has also been demonstrated that PUFA's decrease the transcription of hepatic genes encoding glycolytic and lipogenic enzymes. The effect of the PUFA's on gene expression in the liver and muscle thus leads to increased metabolism and

30 decreased fat storage, helping to prevent weight gain. Energy conversion is mainly located to the mitochondria within the cell. The mitochondria preferentially oxidise medium- and short-chain fatty acids. Energy released is

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Huvudföreläsaren Kassan

converted into ATP, which is used for a large number of  
energy dependent processes. However, mitochondrial energy  
conversion is not 100% efficient, and part of the  
metabolic energy is released as heat. The efficiency of  
5 mitochondrial energy conversion is modulated by  
mitochondrial uncoupling proteins. Further, the PUFA's  
also affect another site for metabolic energy conversion,  
namely the peroxisome also located inside the cell  
membrane. While the main role of mitochondria is the  
10 production of the energy-rich ATP, peroxisomes are more  
active in the generation of heat, while shortening  
polyunsaturated long-chain fatty acids before their  
further oxidation in mitochondria. The net effect is  
increased production of heat instead of increasing the  
15 fat deposits. PUFA's are peroxisome proliferators  
increasing the amount and the activity of peroxisomes.

Moreover, during fasting, a major physiological  
situation leading to the depression of adiposity, energy  
content of fat cells may be reduced by several  
20 mechanisms, like upregulation of mitochondrial uncoupling  
protein 2, see (Millet L et al. J. Clin. Invest.  
100:2665-2670, 1997; Vidal-Puig A. et al. Obesity  
Research 7:133-140, 1999). Moreover, it has been shown  
that reduction of abdominal fat by dietary omega-3 PUFAs  
25 in rats is associated with increased levels of expression  
of uncoupling proteins 2 and 3 in adipose tissue (Oudart  
H. et al. Int. J. Obesity and Metab. Disord. 24 Supp  
1:S130, 2000; Hun C.S. et al. Biochem. Biophys. Res.  
Commun. 259:85-90, 1999). Furthermore, it has also been  
30 shown that a 6 g/day substitution of visible fat by fish  
oil in healthy adults reduces fat mass and increases  
basal lipid oxidation (Couet C, Delarue J, Ritz P,  
Antoine J-M and Lamisse F, 1997, International Journal of

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Obesity 21: 637-643), but at the same time the fish oil <sup>Huyulffers Kassen</sup> had no significant effect on body weight reduction.

#### Summary of the invention

- 5       Based on the present invention a number of aspects are presented in the appended claims. These aspects are;
1.       Use of a new medical product for controlling body weight reduction, for treatment of obesity or an overweight condition.
  - 10      2.       A method for treatment of obesity, an overweight condition or for controlling body weight reduction.
  3.       Use of a food stuff or food supplement for controlling and supporting body weight reduction in a human or an animal.
  - 15      4.       A dietary product for non-medical treatment of obesity, an overweight condition and/or for supporting and controlling weight reduction.
  5.       Use of a dietary food stuff or food supplement for controlling and supporting weight reduction.
  - 20      6.       A method for supplementing a dietary food stuff.

The aspects above are based on at least one of the following features:

- 25       • a fatty acid composition comprising at least one of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or any combinations thereof.
- 30       • a step of adding a fatty acid composition comprising at least one of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic

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According to a first aspect of the invention, the invention relates to the use of a fatty acid composition comprising at least one of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or any combinations thereof, for the production of a medicinal product for controlling body weight reduction, for treatment of obesity or an overweight condition. From research leading to the invention it was surprisingly found that a fatty acid composition according to the invention leads to body weight reduction in mice.

15 In a preferred embodiment, the invention relates to the use of a fatty acid composition comprising (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or a combination of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-  
20 4,7,10,13,16,19-docosahexaenoic acid (DHA), wherein the weight ratio of EPA:DHA in the fatty acid composition is 1:X, where X is equal or greater than 1, for the production of a medicinal product for controlling body weight reduction, treatment of obesity or an overweight  
25 condition. Please note that X being one of an integer or non-integer.

Moreover, from the research leading to the invention it was found that the most preferred effect of the invention concerning weight reduction is accomplished by a fatty acid composition rich in DHA. The term "rich" herein includes more or less a fatty acid composition primary containing DHA (none EPA) and a fatty acid composition where the amount of DHA  $\geq$  EPA. Further, the



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Huvudfaxen, Karsön

term "amount" herein relates to weight or volume of the fatty acid composition. Moreover, the desired pharmacological and/or therapeutic effect may be achieved by the fatty acid composition according to the invention.

5 In addition, as known before food reduction alone will not effectively lead to weight reduction in a human. Suitably, the treatment according to the invention is combined with at least one of calorie restriction, (fasting), dietary and physical exercise or combinations  
10 thereof, that may lead to body weight reduction in a human or an animal. Furthermore, this opens up for a future market for a pharmaceutical, a food stuff and/or a dietary product containing the fatty acid composition according to the invention not only for the purpose of  
15 treating obesity or overweight conditions, but also for the purpose of controlling and supporting body weight reduction (a helping hand for weight control, body weight reduction, preferably in combination with a reduced intake of calories).

20 In a preferred embodiment of the invention, EPA and DHA in the fatty acid composition are present in the composition in an EPA:DHA ratio from 1:1 to 1:8. In a more preferred embodiment the EPA:DHA ratio in the fatty acid composition is from about 1:1 to 1:6. Moreover, the  
25 invention also includes administering a fatty acid composition that is a DHA-product.

In another embodiment, the fatty acids in the composition according to the invention is presented in at least one of esterified form, ethyl ester form, salt form  
30 and free acid form, or any combinations thereof. In a preferred embodiment, the fatty acid composition is comprised of a combination of EPA and DHA in triglyceride form.

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Huyudfaxen Kassan

Moreover, it should be pointed out that the fatty acid composition is administered to a human or an animal, preferably orally, in the form of for instance a pill or a soft capsule. However, the medicinal product according to the invention may also be produced for administration through any other route where the active ingredients may be efficiently absorbed and utilized, e.g. intravenously, subcutaneously or intramuscularly.

25 In a preferred embodiment of the invention the treatment or intake of a medicinal product is carried out together with a reduced intake of calories for a human or an animal. Suitably, the reduced intake of calories is also combined with physical exercise. If the  
30 administration of a medicinal product according to the invention, to a human or an animal, goes hand-in-hand with a reduced intake of calories the reduction in body weight will be more effective.

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Huvudföken Kesson

In another preferred embodiment of the invention, the fatty acid composition comprising at least one of EPA and DHA or any combination thereof is administered in a daily dosage in the interval 10-40 % of the total lipid content of a daily diet for a human or an animal. This means that up to 40 % of the total lipid content of a daily diet may be replaced by the fatty acid composition according to the invention. Please note that, another way of defining the daily dosage of the fatty acid composition is presented above.

In another preferred embodiment of the invention, the fatty acid composition comprising DHA or a combination of EPA and DHA is administered in an amount providing a daily dosage of 1 g to 15 g of said fatty acid composition. In a more preferred embodiment between 2 and 10 g of said fatty acid composition is administered per day, and in a most preferred embodiment between 2 and 6 g of said fatty acid (per day). As has been shown in the experiments the effect of the fatty acid composition according to the invention seems to be extra strong at high doses. The medicinal product or pharmaceutical composition or pharmaceutical preparation according to the invention may also comprise other substances such as an inert vehicle, or pharmaceutical acceptable adjuvants, carriers, preservatives etc., which are well known in those skilled in the art. Additionally, the medicinal product may be administered to an animal such as a pet or a horse.

According to a second aspect of the invention, the invention relates to a method for treatment of obesity, and overweight condition or for controlling body weight reduction, wherein an effective amount of a fatty acid composition comprising at least one of (all-Z omega-3)-

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Huvudfoxen Kassa

5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z  
omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or  
combinations thereof, is administered to a human or an  
animal. Herein, "an effective amount" also includes a  
therapeutically or a pharmaceutically active amount of  
the fatty acid composition. This expression relates to a  
dose of said fatty acid composition that will lead to the  
desired pharmacological and/or therapeutic effect. The  
desired pharmacological and/or therapeutic effect is, as  
stated above, achieved by the fatty acid composition  
according to the invention.

In a preferred embodiment of the method, said fatty  
acid composition comprising DHA or a combination of EPA  
and DHA, wherein the weight ratio of EPA:DHA in the fatty  
acid composition is 1:X, where X is equal or greater than  
1. This method leads to the same advantages and  
possibilities as mentioned before. Thus, the embodiments  
described above is also included for the method according  
to the invention concerning treatment of obesity, an  
overweight condition an/or for controlling and/or  
reducing body weight. Additionally, in another embodiment  
of the method according to the invention, with the aim to  
reduce body weight, said fatty acid composition is  
administered in a daily dosage that corresponds to at  
least 10 % of the total lipid content of a daily diet for  
a human or an animal.

According to a third aspect of the invention, the  
present invention relates to the use of a fatty acid  
composition comprising at least one of (all-Z omega-3)-  
5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z  
omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or  
any combinations thereof, for the production of a food

In a specific embodiment, the present invention relates to the use of a fatty acid composition comprising

5 (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid  
(DHA) or a combination of (all-Z omega-3)-5,8,11,14,17-  
eicosapentaenoic acid (EPA) and (all-Z omega-3)-  
4,7,10,13,16,19-docosahexaenoic acid (DHA), wherein the  
weight ratio of EPA:DHA in the fatty acid composition is  
10 1:X, where X is equal or greater than 1, for the  
production of a food stuff or food supplement for  
controlling body weight and for supporting weight  
reduction. The most preferred effect of the invention  
related to body weight reduction is also there  
15 accomplished by the use of DHA or a fatty acid  
composition rich in DHA, i.e. more DHA in relation to  
EPA. One advantage of manufacturing and selling a food  
stuff for at least one of reducing body weight,  
controlling and supporting body weight reduction is that  
20 such a food stuff will be more easily accessible for  
people. They preferably buy the product or supplement in  
a health store and/or a supermarket, and they do not need  
to visit a doctor.

In a preferred embodiment of the invention, EPA and  
25 DHA in the fatty acid composition are present in the  
composition in an EPA:DHA ratio from 1:1 to 1:8. In a  
more preferred embodiment the EPA:DHA ratio in the fatty  
acid composition is from about 1:1 to 1:6. In another  
embodiment of the invention, the fatty acid composition  
30 is a DHA-product.

Moreover, in another embodiment, the fatty acids in the composition according to the invention is presented in at least one of esterified form, ethyl ester form,

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salt form and free acid form, or any combinations thereof. In a preferred embodiment, the fatty acid composition is comprised of a combination of EPA and DHA in triglyceride form. Huvudfaxen Kessan

5 In another embodiment, at least one of EPA and DHA is obtained from at least one of vegetable, microbial and animal origins. The food stuff or food supplement includes therefore for instance a fatty acid composition comprising at least one of a DHA-containing microbial oil and a mixture of an DHA-containing oil from microbial 10 origin and a EPA-containing oil from a marine origin. Further, the fatty acid composition according to the invention may additionally also comprise other fatty acids as mentioned before. Suitably, at least a part of 15 the EPA and/or DHA is produced from a marine oil, preferably a fish oil.

Furthermore, in another embodiment of the food stuff or food supplement the fatty acid composition is produced from a marine oil, such as a fish oil. Moreover, it 20 should be pointed out that the fatty acid composition is administered to a human or an animal, preferably orally. However, the food stuff or food supplement according to the invention may also be produced for administration though any other route where the active ingredients may 25 be efficiently absorbed and utilized, e.g. intravenously, subcutaneously, intramuscularly, intranasally, rectally, vaginally or topically.

In a preferred embodiment of the invention, the intake of a food stuff or food supplement is carried out 30 together with a reduced intake of calories for a human or an animal. Herein an animal is a pet or a horse. Suitably, the reduced intake of calories is also combined with physical exercise. If the administration of a food

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Huvudtaxen Kassen

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stuff or food supplement according to the invention, to a human or an animal, goes hand-in-hand with a reduced intake of calories the reduction in body weight will be more effective.

5 In another preferred embodiment of the invention, said fatty acid composition is administered in a daily dosage in the interval 10-40 % of the total lipid content of a daily diet for a human or an animal. This means that 10 up to 40 % of the total lipid content of a daily diet  
10 may be replaced by the fatty acid composition according to the invention.

In another preferred embodiment of the invention, the fatty acid composition comprising DHA or a combination of EPA and DHA is administered in an amount providing a  
15 daily dosage of 1 g to 15 g of said fatty acid composition. In a more preferred embodiment between 2 and 10 g of said fatty acid composition is administered per day, and in a most preferred embodiment between 2 and 6 g of said fatty acid (per day). As mentioned before the  
20 effect of the fatty acid composition according to the invention seems to be extra strong at high doses.

In another preferred embodiment, the food stuff or food supplement is in form of capsule, preferably a gelatine capsule which capsule is flavoured. This  
25 embodiment also includes a capsule, wherein both the capsule and the encapsulated fatty acid composition, preferably a fish oil, is flavoured. By flavouring the capsule as above, the product will become more attractive to the user.

30 Further, human beings are not designed to lose body weight only during fasting. A sound strategy for losing weight should also take into account measures of energy expenditure and dietary advice based on the individual.

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Muvudtalen Kassar

Thus, according to a fourth aspect of the invention, the present invention relates to a dietary product containing a fatty acid composition comprising at least one of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or any combinations thereof, for non-medical treatment of obesity, an overweight condition and/or for supporting and controlling body weight reduction.

In a preferred embodiment of the invention, the dietary product containing a fatty acid composition comprising (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or a combination of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA), wherein the weight ratio of EPA:DHA in the fatty acid composition is 1:X, where X is equal or greater than 1, for non-medical treatment of obesity, an overweight condition and/or for supporting and controlling body weight reduction.

In another embodiment of the invention, the dietary product is a weight-watching product or a slimming product.

In another embodiment according to the dietary product, the combination of EPA and DHA are present in the composition in an EPA:DHA ratio from about 1:1 to 1:8, preferably in an EPA:DHA ratio from 1:1 to 1:6.

In another embodiment of the dietary product, at least one of EPA and DHA is obtained from at least one of vegetable, microbial and animal origins or combinations thereof. Preferably, the fatty acid composition is produced from a marine oil, for instance a fish oil. Suitably, the intake of the dietary product is combined with a reduced intake of calories for a human and/or



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## Huvudfaxen Kasse

In a preferred embodiment of the dietary product, said fatty acid composition is administered in a daily dosage that corresponds to at least 10 % of the total lipid content of a daily diet for a human or an animal.

In a preferred embodiment, the use of a fatty acid composition comprising (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or a combination of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA), wherein the weight ratio of EPA:DHA in the fatty acid composition is 1:X, where X is equal or larger than 1, in the manufacture of a dietary product for controlling body weight and for supporting weight reduction in a human.

30 In a preferred embodiment of the method for supplementing a dietary product, the invention relates to the step of adding a fatty acid composition comprising (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid

Most of the dietary products on the market containing small amounts of saturated fatty acids. The invention opens up for possibilities to incorporate the fatty acid composition according to the invention in a new or already existing dietary product. In a preferred embodiment of the invention a fish oil is incorporated in a dietary product. Thus, this may be a faster way to reach the market with a dietary product, which product has the aim of supporting, controlling and/or trigger body weight reduction.

Moreover, obesity, having an excessive amount of body fat, is herein defined as a body mass index over 30, wherever overweight is defined as a body mass index exceeding 25. Obesity also includes visceral or general obesity that is due to genetic predisposition, sometimes described as the thrifty genotype. Obesity caused by life cycle and environment, such as diets with high fat content or a high calorie content, or lack of exercise, can also be treated as described herein. As used herein the term "treatment" means both treatment having a curving or alleviating purpose and the treatment of obesity or an overweight condition can be made either acutely or chronically. By chronically treatment is meant treatment that continues for more than some weeks or years. Moreover, the present invention also includes

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preventing body weight gain by administering a fatty acid composition according to the invention.

5 In the studies and examples below reference is made to the accompanying drawings, where all figures concern studies performed on mice. The studies were performed in order to demonstrate that a treatment with a fatty acid composition comprising at least one of EPA and DHA or any combinations thereof, reduces body weight. Herein  
10 reference is made to the accompanying drawings, on which:

20 Figure 2A shows the composition of semi synthetic  
high-fat diets (20% w/w fat) containing flaxseed oil  
(Ln), flaxseed oil with a higher dose of EPAX2050TG  
(Ln+FO) and flaxseed oil with a low dose of EPAX2050TG  
(Ln+FO Low), given to the different groups of mice.  
25 Figure 2B shows the total body weight after two months of  
treatment.

Figure 3A and 3B show the composition (in % w/w) of semi synthetic high fat (20% fat) diets containing flaxseed oil (Ln), corn oil (K), EPAX 1050TG (high in  
30 DHA) (D), EPAX 4510TG (high in EPA) (E), corn oil + EPAX 1050TG (K+D), and corn oil + EPAX 4510 (K+E), respectively the composition (in % of total energy content of the diet) of standard diet (ST) and

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**Hilvafærni Kassan**

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A number of preferred embodiments of the invention, were performed in order to demonstrate that treatment with fatty acid compositions, comprising at least one EPA and DHA or any combinations thereof, reduces body weight.

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### Examples

Experiments performed on mice:

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5 In the first study, the effects of an omega-3 fatty acid composition containing EPA and DHA on the body weight were studied. A mixture containing 20% EPA and 50% DHA was used. Groups (n=7) of adult male mice (C57BL/6J mouse) fed standard feeding diet (4% fat), were randomly assigned one of four different types of semi synthetic high-fat (20% fat) diets where the fat component was: Group 1) Lard (L), Group 2) Lard plus EPAX2050TG (L+FO: EPAX 2050TG formed 44 % w/w of total lipid content), Group 3) Flaxseed oil (18:3n-3 forms about 50% of total lipids; Ln) and Group 4) Flaxseed plus EPAX2050TG (Ln+FO; EPAX 2050TG formed 44 % w/w of total lipid content). Note that FO herein means various EPA and DHA concentrates (EPAX...TG) used in these studies. The animals were fed the different diets mentioned above during 1 month and the composition of the feeding containing flaxseed oil with (Ln+FO) or without EPAX2050TG (Ln) is shown in figure 1A. After the study, the total body weight was reduced in Group 2 (L + FO) vs. Group 1 (L); and Group 4 (Ln + FO) vs. Group 3 (Ln), and the difference was statistically significant in Group 4 vs. 3, as evident from figure 1B. The body weights of mice before treatment were similar in all the groups. The mice's given flaxseed oil plus EPAX2050TG had decreased by about 10% in body weight compared to the mice's only given flaxseed oil.

30 This study shows that treatment with a fatty acid composition containing EPA and DHA, wherein the amount of DHA  $\geq$  EPA, leads to weight reduction.

Study 2: weight reduction

In the second study the effect of the dose of an omega-3 fatty acid composition comprising a combination of EPA and DHA (20% EPA and 50% DHA) in relation to reduction on body weight was studied. Groups (n=7) of adult male mice by standard chow diet (4% fat), were randomly assigned one of three different semi synthetic high-fat (20% fat), for two months. In this experiment group 1) was given Flaxseed oil (Ln), Group 2) Flaxseed oil plus a higher dose of EPAX2050TG (Ln+FO; EPAX2050TG formed 44 % w/w of total lipid content), and Group 3) Flaxseed oil plus a lower dose of EPAX2050TG (Ln+FO Low; EPAX 2050TG formed 15 % w/w of total lipid content), as the fat component herein. The composition of the diets containing only flaxseed oil (Ln) and flaxseed oil with a higher (Ln+FO) respectively a lower (Ln+FO Low) dose of EPAX2050TG is shown in figure 2A. At the end of the study the total body weight was reduced only in group 2, the group given flaxseed oil with a higher dose of EPAX2050TG, as evident from figure 2B.

The results of the second study are consistent with the first one, with weight reduction in the group given a fatty acid composition wherein the weight ratio of DHA  $\geq$  EPA. Moreover, the results from the present study also shows that administration of a fatty acid composition rich in DHA in very low doses did not resulting significant decrease of body weight in rats fed a high fat diet.

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Study 3: weight reduction

Hjuddöfen Kossan

In this study potential differences in effects between a DHA-enriched omega-3 product (herein presented as a fatty acid composition comprising 10% EPA and 50% DHA (EPAX2050TG concentrate), an EPA product (rich in EPA, herein presented as a fatty acid composition comprising 45% EPA and 10% DHA; EPAX4510TG) and plant oils containing omega-6 fatty acids, were studied. Groups (n=7) of adult male mice (C57BL/6J mouse), fed standard chow diet (4% fat), were randomly assigned one of six different types of semisynthetic high-fat (20% fat) diets where the fat component was: group 1) Flaxseed oil (plant omega-3) (Ln), group 2) Corn oil (plant omega-6) (K), group 3) EPAX 1050 (high in DHA) (D), group 4) EPAX 4510TG (high in EPA) (E), group 5) Corn oil + EPAX 1050TG (K+D), and group 6) Corn oil + EPAX 4510TG (K+E). One control group maintained on standard diet (-ST) was also included. The animals were fed the different diets during 2 months. The composition of diets are shown in figures 3A and 3B. As can be seen in figure 3C, the food consumption was about 70 KJ per day and animal during the 8 weeks of treatment. The results in figure 3D show that treatment with a fatty acid composition containing at least EPA and DHA or combinations thereof leads to weight reduction. Weight reduction has been obtained in animals fed EPAX 1050TG (a fatty acid composition rich in DHA) or EPAX 4510TG (a fatty acid composition rich in EPA) in addition (44% of total fat content formed by the product) to corn oil. However, the effect of EPAX 1050TG (high in DHA) was stronger compared with EPAX 4510TG. Moreover, the body weights of the mice fed corn oil plus EPAX 1050TG (high in DHA) had decreased by about 15% in weight. The animals do not tolerate high-fat (20%)

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semisynthetic diet containing only EPAX 1050TG (high in DHA) as the only lipid constituent. Only 1 out of 7 mice fed EPAX 1050TG survived longer than 4 weeks on the diet. The mice's got to slimy. All of the rats fed only EPAX 4510TG containing diet survived but looked unhealthy.

The results of the third study shows that the weight lowering effect of a fatty acid composition comprising about 10% EPA and 50% DHA (a fatty acid composition rich in DHA), was stronger compared to a fatty acid composition comprising about 45% EPA and 10% DHA (rich in EPA). Furthermore, weight reduction due to corn oil was similar to the reduction due to a fatty acid composition comprising about 20% EPA and 50% DHA in flaxseed oil (in the 1<sup>st</sup> and the 2<sup>nd</sup> experiment) and stronger than the reduction due to a fatty acid composition comprising about 20% EPA and 50% DHA in lard (in the 1<sup>st</sup> experiment). Once more above states a best mode using a product rich in DHA, preferably DHA  $\geq$  EPA. These results also suggest a specific weight-lowering effect of an omega-3 product of marine origin as compared with plant oils (both omega-3 and omega-6) and saturated fats (lard).

#### Doses of the fatty acid composition

Concerning the dose, the results from mice may be extrapolated to humans, as far as the relative content of the fatty acid composition according to the invention, for instance an fatty acid composition containing EPA and DHA or any combinations thereof, in the diet is concerned. In the studies before a semi-synthetic diet containing 20% (w/w) fat was used, and effect on weight reduction was observed when at least about 28% of the lipid content was replaced by a fatty acid composition



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the fatty acid composition according to the invention.  
This means about 3 g of the fatty acid composition per  
day, in a very low calorie diet of 1000kcal/day with 18 %  
calories from fat.

In another preferred embodiment of the invention, said reduced intake of calories is reduced to at least 800 kcal (2520 KJ per day) or less, for a short and drastic treatment of obese patients (adult persons). In a more preferred embodiment said fatty acid composition comprising at least one of EPA and DHA or any combinations thereof is administered in a daily dosage from (corresponding to) 10 up to 40 % of the total lipid content of a daily diet for a human. Moreover, to achieve a improved result the lipid content of the diet may be lowered to at least 15 % of its energy content. The fatty acid composition according to the invention is preferably administered daily, divided in dosage, for periods up to 1-5 years.

25 On the other hand, the dosage of the fatty acid composition according to the invention may also be related to the amount of omega-3 fatty acids consumed by for instance Eskymo's or similar native people. Therefore, in an another embodiment of the invention said  
30 fatty acid composition comprising at least one of EPA and DHA or any combinations thereof, is administered in an amount providing a daily dosage of 1 g to 15 g of said

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fatty acid composition. More preferred in an amount of <sup>10</sup> to 10 g, and most preferred between 2 and 6 g per day.

#### Discussion

5 The results shows that a fatty acid composition comprising at least one of EPA and DHA or any combinations thereof, reduces body weight. The weight lowering effect of a product according to the invention that is rich in DHA is stronger compared to a product  
10 containing more EPA than DHA. Moreover, preferably a specific weight-lowering effect is achieved of a fatty acid composition according to the invention of marine origin. Further, based on the results, calculations of doses and commercial value, the use of the fatty acid  
15 composition according to the present invention preferably may go hand-in-hand with a dietary regimen of calorie reduction. It is also obvious to expect the same weight lowering effect on both humans and animals by administering the fatty acid composition according to the  
20 invention.

The invention shall not be limited to the shown embodiments and examples.

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Huvudfaxen Kössön

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Claims

1. Use of a fatty acid composition comprising at least on  
5 of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid  
(EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic  
acid (DHA) or any combinations thereof, for the  
production of a medicinal product for controlling body  
weight reduction, and for treatment of obesity or an  
10 overweight condition.

2. Use according to claim 1, wherein the weight ratio of  
EPA:DHA in the fatty acid composition is 1:X, where X is  
equal or greater than 1.

15 3. Use according to claim 1, wherein the combination of  
EPA and DHA are present in the composition in an EPA:DHA  
ratio from 1:1 to 1:8, preferably in an EPA:DHA ratio  
from 1:1 to 1:6.

20 4. Use according to claim 1, wherein the fatty acids in  
the composition is presented in at least one of  
esterified form, ethyl ester form, salt form and free  
acid form, or any combinations thereof.

25 5. Use according to claim 1, wherein at least one of EPA  
and DHA is obtained from at least one of vegetable,  
microbial and animal origins or combinations thereof.

30 6. Use according to claim 1, wherein at least a part of  
the EPA and/or DHA is produced from a marine oil,  
preferably a fish oil.

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Huvudingen Kesson

7. Use according to claim 1, wherein the fatty acid composition is produced from a marine oil.

5 8. Use according to claim 1, wherein the fatty acid composition is comprised of a combination of EPA and DHA in triglyceride form.

10 9. Use according to claim 1, wherein the fatty acid composition is administered orally to a human or an animal.

15 10. Use according to claim 9, wherein the treatment is carried out together with a reduced intake of calories for a human or an animal.

20 11. Use according to claim , wherein said fatty acid composition is administered in a daily dosage in the interval 10-40 % of the total lipid content of a daily diet for a human or an animal.

25 12. Use according to claim 1, wherein said fatty acid composition is administered in an amount providing a daily dosage of 1 g to 15 g of said fatty acid composition, preferably between 2 and 6 g for a human.

30 13. A method for treatment of obesity, an overweight condition or for controlling body weight reduction, wherein an effective amount of a fatty acid composition comprising at least one of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or any combinations thereof, is administered to a human or an animal.

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20 18. A method according to claim 13, wherein at least one of EPA and DHA is obtained from at least one of vegetable, microbial and animal origins.

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Huvudfaxen Kassen

21. A method according to claim 13, wherein the treatment is carried out together with a reduced intake of calories for the human or an animal.
- 5 22. A method according to claim 13, wherein said fatty acid composition is administered in a daily dosage that corresponds to at least 10 % of the total lipid content of a daily diet for a human or an animal.
- 10 23. Use of a fatty acid composition comprising at least one of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or any combinations thereof, for the production of a food stuff or food supplement for
- 15 controlling and supporting body reduction.
24. Use according to claim 23, wherein the weight ratio of EPA:DHA in the fatty acid composition is 1:X, where X is equal or greater than 1.
- 20 25. Use according to claim 23, wherein the combination of EPA and DHA are present in the composition in an EPA:DHA ratio from about 1:1 to 1:8, preferably in an EPA:DHA ratio from 1:1 to 1:6.
- 25 26. Use according to claim 23, wherein the fatty acids in the composition is presented in at least one of esterified form, triglyceride form, ethyl ester form, salt form and free acid form, or any combinations
- 30 thereof.

27. Use according to claim 23, wherein the fatty acid composition is comprised of a combination of EPA and DHA presented in triglyceride form.

28. Use according to claim 23, wherein at least one of EPA and DHA is obtained from at least one of vegetable, microbial and animal origins or combinations thereof.

29. Use according to claim 23, wherein the at least a  
10 part of the EPA and/or DHA is produced from a marine oil,  
preferably a fish oil.

30. Use according to claim 23, wherein the fatty acid composition is produced from a marine oil.

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31. Use according to claim 23, wherein the composition is administered orally to a human or an animal.

32. Use according to claim 31, wherein the control of  
20 body weight and fat reduction is carried out together  
with a reduced intake of calories for a human or an  
animal.

33. Use according to claim 23, wherein said fatty acid  
25 composition is administered in a daily dosage that  
corresponds to at least 10 % of the total lipid content  
of a daily diet for a human or an animal.

34. Use according to claim 23, wherein the food stuff or  
30 food supplement is in form of a gelatine capsule, which  
capsule is flavoured.



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35. Use according to claim 23, wherein said fatty acid composition comprising DHA or a combination of EPA and DHA is administered in an amount providing a daily dosage of 1 g to 15 g of said fatty acid composition, preferably  
5 between 2 and 6 g to a human.

36. A dietary product containing a fatty acid composition comprising at least one of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-  
10 4,7,10,13,16,19-docosahexaenoic acid (DHA) or any combinations thereof, for non-medical treatment of obesity, an overweight condition and/or for supporting and controlling body weight reduction.

15 37. A dietary product according to claim 36, wherein the weight ratio of EPA:DHA in the fatty acid composition is 1:X, where X is equal or greater than 1.

20 38. A dietary product according to claim 36, wherein the dietary product is a weight-watching product or a slimming product.

39. A dietary product according to claim 36, wherein the combination of EPA and DHA are present in the composition  
25 in an EPA:DHA ratio from about 1:1 to 1:8, preferably in an EPA:DHA ratio from 1:1 to 1:6.

40. Use according to claim 36, wherein at least one of EPA and DHA is obtained from at least one of vegetable,  
30 microbial and animal origins or combinations thereof.

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41. A dietary product according to claim 36, wherein the fatty acid composition is produced from a marine oil, preferably a fish oil.

5 42. A dietary product according to claim 36, wherein intake of the dietary product is combined with a reduced intake of calories for a human and/or together with physical activity.

10 43. A method according to claim 36, wherein said fatty acid composition is administered in a daily dosage that corresponds to at least 10 % of the total lipid content of a daily diet for a human or an animal.

15 44. Use of a fatty acid composition comprising comprising at least on of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or any combinations thereof, in the manufacture of a dietary  
20 product for controlling and supporting weight reduction in a human.

45. Use according to claim 44, wherein the weight ratio of EPA:DHA in the fatty acid composition is 1:X, where X  
25 is equal or greater than 1.

46. A method for supplementing a dietary product comprising the step of  
adding a fatty acid composition comprising at least on of  
30 (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or any combinations thereof, to the supplement

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product for controlling and supporting weight reduction  
in a human.

47. A method according to claim 46, wherein the weight  
5 ratio of EPA:DHA in the fatty acid composition is 1:X,  
where X is equal or larger than 1.

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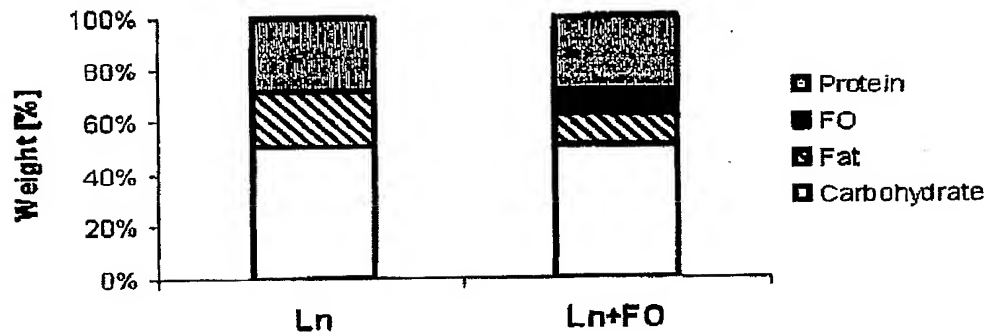
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## Abstract

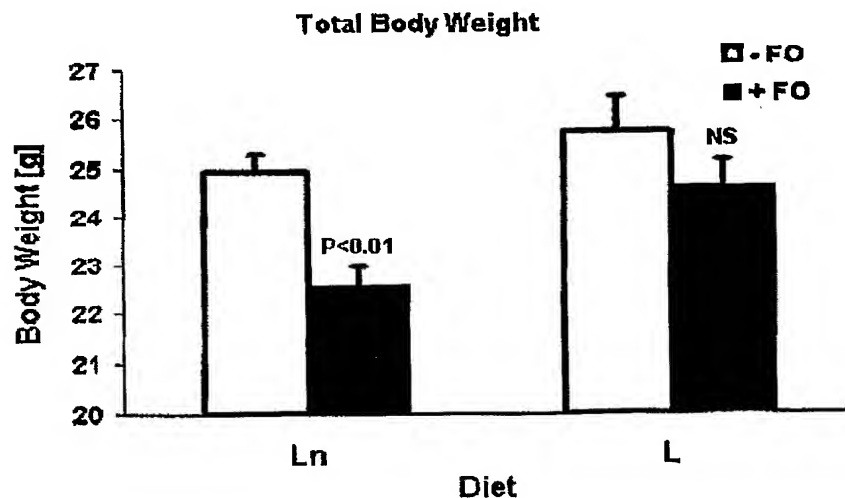
This invention relates to a method for treatment of obesity, an overweight condition or for controlling body weight reduction, wherein an effective amount of a fatty acid composition comprising at least one of (all-Z omega-3)-5,8,11,14,17-eicosapentaenoic acid (EPA) and (all-Z omega-3)-4,7,10,13,16,19-docosahexaenoic acid (DHA) or any combinations thereof, is administered to a human or an animal. The present invention also relates to use of the fatty acid composition above for manufacture of a medicinal product for controlling body weight reduction, and for treatment of obesity or an overweight condition. Moreover, the present invention also relates to use of a fatty acid composition comprising at least one of EPA and DHA or any combinations thereof, for the manufacture of a food stuff or food supplement for controlling and supporting body weight reduction. Additionally, the present invention also includes a dietary product containing a fatty acid composition comprising at least one of EPA and DHA or any combinations thereof, for non-medical treatment of obesity, an overweight condition and/or for supporting and controlling body weight reduction. Finally, the present invention relates to a method for supplementing a dietary product with a fatty acid composition mentioned above.

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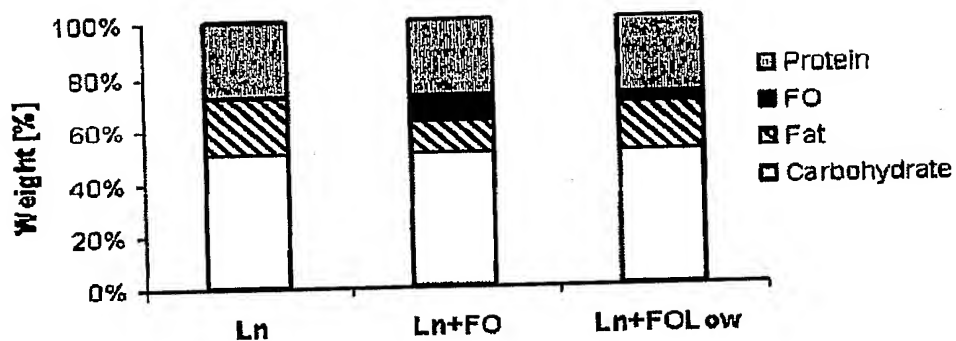
Composition of the semisynthetic high-fat diets (20 % w/w fat) containing flaxseed oil (Ln) and flaxseed oil with EPAX 2050TG; FO (Ln+FO)

*Fig. 1A*

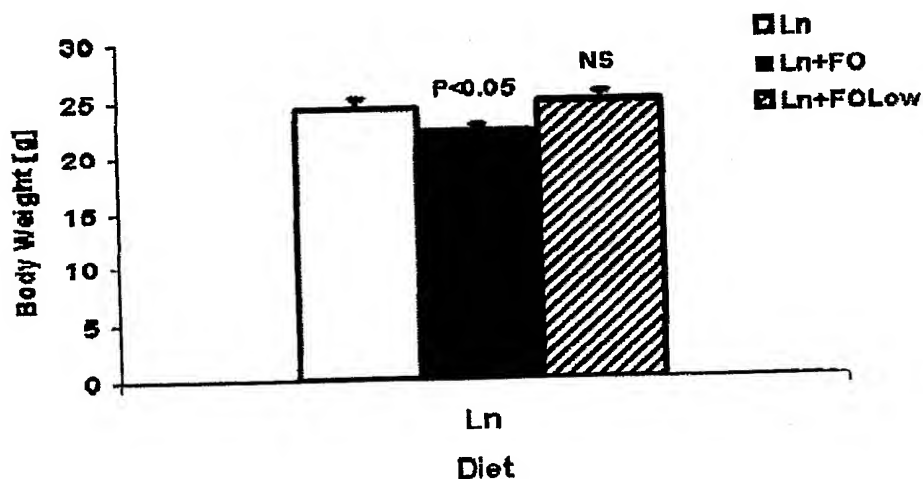
Total body weight after one month of treatment. Lard (L), Lard plus EPAX2050TG (L+FO), Flaxseed oil (Ln) and Flaxseed plus EPAX2050TG (Ln+FO)

*Fig. 1B*

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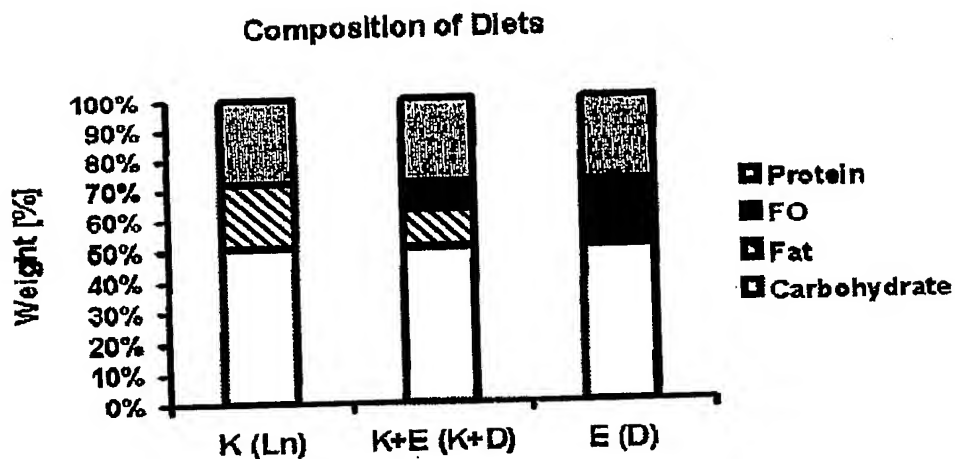
Composition of semisynthetic high-fat diets (20 % w/w fat) containing flaxseed oil (Ln), flaxseed oil with a higher dose of EPAX2050TG (Ln+FO) and flaxseed oil with a lower dose of EPAX2050TG (Ln+FO Low)

*Fig. 2A*

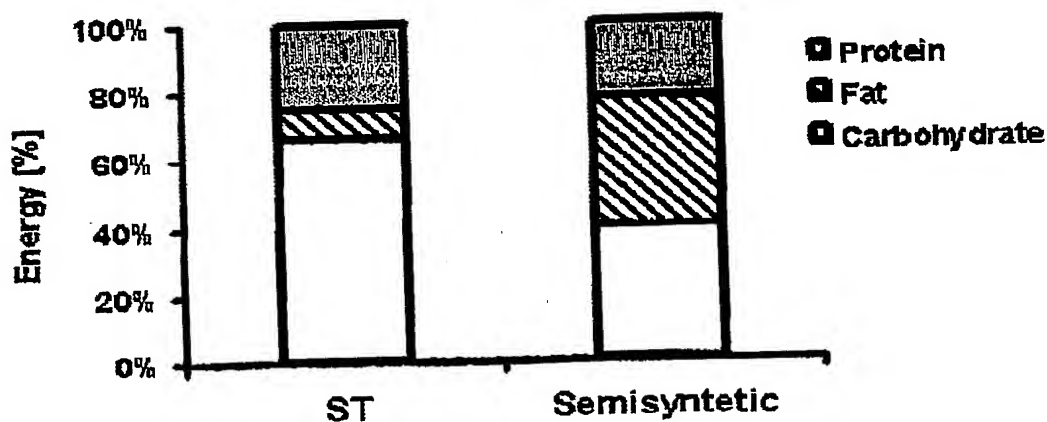
Total body weight after two months of treatment. Flaxseed oil (Ln), Flaxseed oil plus a higher dose of EPAX2050TG (Ln+FO) and Flaxseed oil plus a lower dose of EPAX2050TG (Ln+FO Low).

*Fig. 2B*

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Composition of semi synthetic high-fat (20 % w/w fat) diets containing Flaxseed oil (Ln), Corn oil (K), EPAX 1050TG (high in DHA) (D), EPAX 4510TG (high in EPA) (E), Corn oil + EPAX 1050TG (K+D), and Corn oil + EPAX 4510TG (K+E).

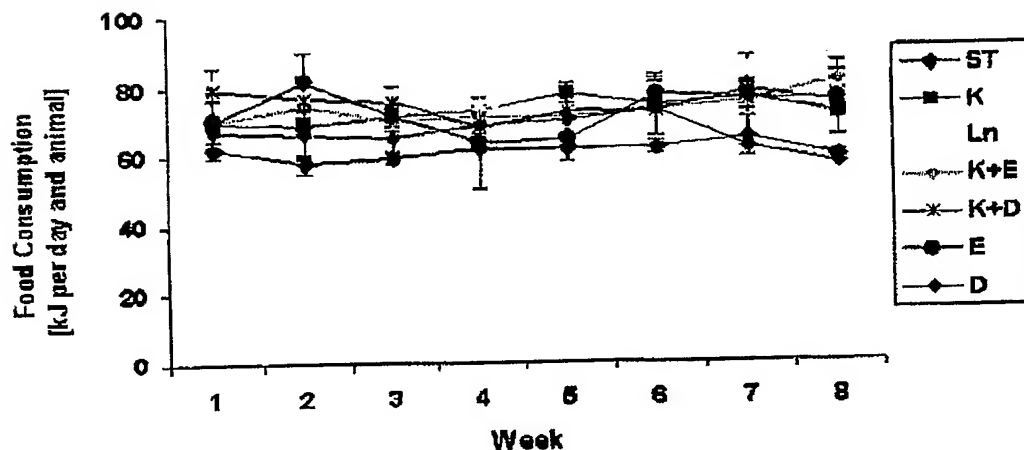
*Fig. 3A*

Composition of standard diet (ST) and semisynthetic diet.

*Fig. 3B*

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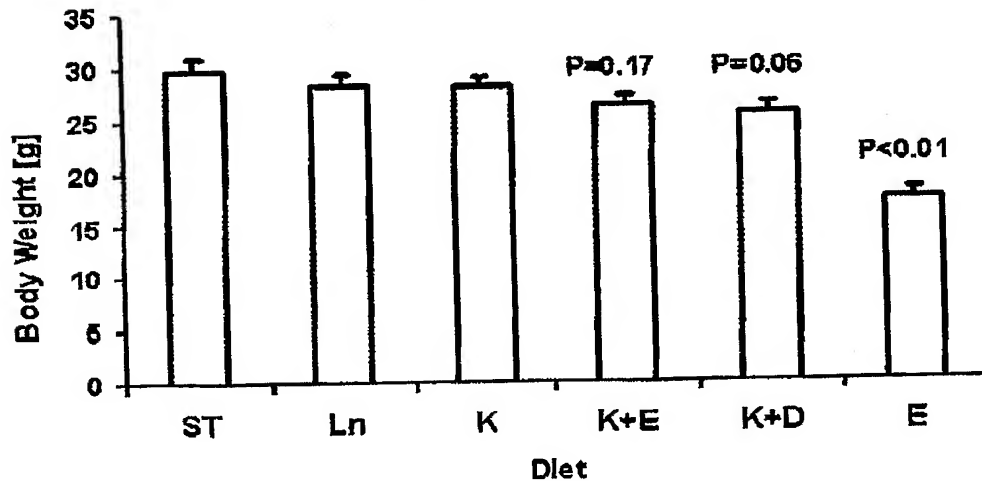
## Food Consumption



Food consumption per day and animal during 8 weeks.

Fig. 3C

## Total Body weight



Total body weight after two months of treatment compared to a control group (ST). Flaxseed oil (Ln), Corn oil (K), EPAX 1050TG (high in DHA) (D), EPAX 4510TG (E), Corn oil + EPAX 1050TG (K+D), and Corn oil + EPAX 4510TG (K+E).

Fig. 3D